AN INTRACARDIAC CATHETER WITH INFLATABLE BALLOON FOR PRODUCING INCREASED VENOUS PRESSURES IN THE VENAE CAVAE OF MAN [1]

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Pertinent to the problem of edema formation in congestive heart failure are the observations, largely in animals (1–5), which indicate that the renal excretions of water and electrolytes are decreased during induced venous congestion, either of the kidney alone or of venous areas including the kidneys. These observations suggested the desirability of studying the excretion of water and electrolytes in man in response to increased congestion and pressure in various parts of the venous system. In order to pursue such a study, a method was developed for producing controlled increases in venous pressure in the venae cavae, specifically in the superior vena cava and in the inferior vena cava at levels including and excluding the renal veins. This paper is a report of the method, which is based upon the use of a "balloon" catheter.

METHODS

A "balloon" catheter was constructed by fashioning a thin latex-rubber balloon about the proximal opening of a double lumen intracardiac catheter, while the distal opening was left open for the recording of pressures (Figure 1). The catheter is introduced into the superior or inferior vena cava of man by the technique of cardiac catheterization and positioned so that the balloon is in the desired location. The balloon is inflated with a dilute (20 per cent) solution of diodrast so that its location is readily determined by fluoroscopic examination (Figure 2). When the balloon was inflated in the inferior vena cava changes in distal venous pressure were measured in the femoral vein by a saline manometer and in the inferior vena cava, through the distal lumen of the catheter, by an optical recording system; when inflated in the superior vena cava, distal venous pressure was measured in the antecubital veins by a saline manometer.

As the pressure rises in the vena cava distal to the inflated balloon, the blood stream usually carries the balloon forward and often into the right atrium. When this occurs the elevated venous pressure in the distal veins promptly falls. An inflated balloon in the inferior vena cava is carried upward into the right atrium, with a great deal of slack catheter, and tends to move toward the tricuspid valve. On such occasions the balloon has been quickly deflated for fear that it might block completely the flow of blood. Such upward "riding" has been prevented by stiffening the catheter with a steel stylette, threaded into the proximal-lumen section of the catheter after the catheter has been positioned. The stylette only partially occupies the lumen and the diodrast solution is still readily introduced and withdrawn. In the superior vena cava the inflated balloon is also carried forward, but usually only to the extent of taking up the slack in the catheter. This may carry the balloon into the right atrium, but not as far as the tricuspid valve and stylettes are not required. Regardless of its location, the position of the balloon is repeatedly checked by fluoroscopy to determine that it remains in the desired position.

The balloon is inflated slowly, over the course of several minutes, to the extent required to produce the desired rise in distal venous pressure. Rapid inflation to a degree whereby most of the vena caval flow is suddenly obstructed can reduce the cardiac output so markedly that syncope may result. In the early observations, before this fact was fully realized, threatened syncope occurred in five subjects, as indicated by the onset of bradycardia, sweating, faintness, weakness and a fall in blood pressure, as low as 62/48 mm. Hg in one subject and 81/46 mm. Hg in another. In all instances

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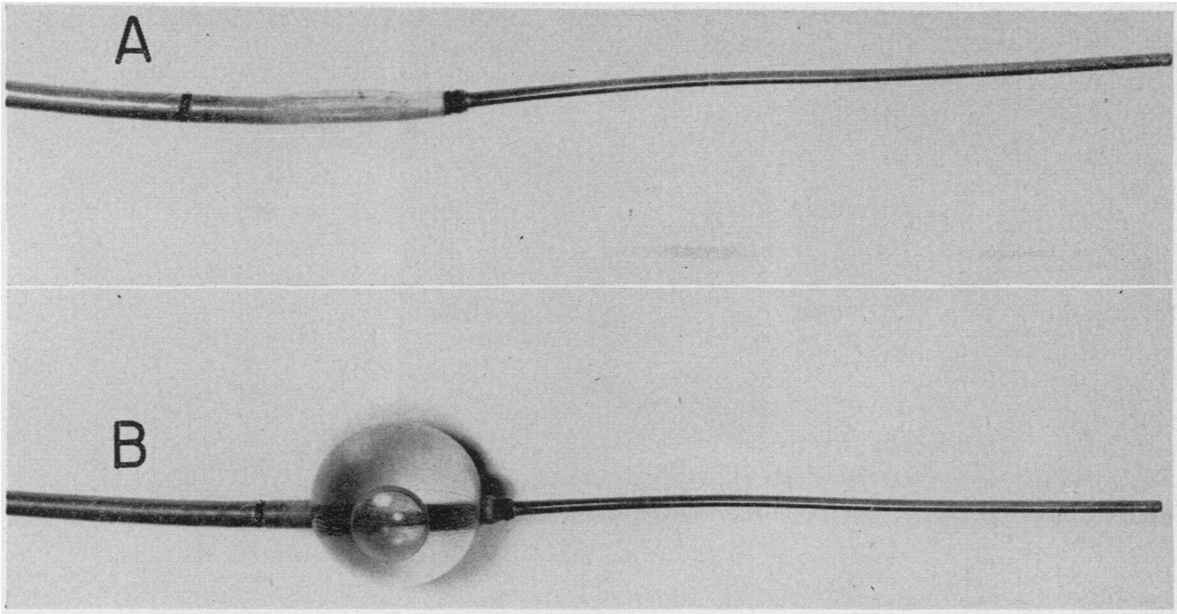

FIG. 1. PHOTOGRAPH OF DISTAL ONE-FOURTH OF "BALLOON" CATHETER

A. Balloon deflated and catheter ready for introduction into a peripheral vein. *B*. Balloon inflated with 8 ml. of 20 per cent diodrast solution. The circular highlight in the balloon is the air bubble formed by the air initially trapped in the lumen of the catheter.

the balloon was quickly deflated with prompt and apparently complete recovery. In several instances the balloon was then reinflated more slowly and distal venous pressures of 200 mm. saline were produced and maintained for 30 minutes without symptoms or change in arterial pressure.

In view of these experiences the procedure was adopted of inflating the balloon at a rate of 1 ml. per minute until the distal venous pressure reached 100 mm. saline and thereafter at a rate of 0.5 ml. per minute until the desired distal venous pressure, usually 170 to 250 mm. saline, was reached. Under such circumstances the arterial blood pressure and heart rate (Figure 3) remained virtually unchanged and no untoward symptoms appeared. Indeed, the subjects were unaware that anything had been done. Nevertheless, even when the balloon is inflated slowly, the blood pressure and heart rate should be determined repeatedly and the patient watched for evidence of circulatory distress. Upon the appearance of any untoward sign or symptom the balloon should be deflated immediately.

It quickly became apparent that the balloon had to be inflated to a considerable degree before the pressure rose in the distal veins. Thus, to obtain pressures in the range of 200 mm. saline in the inferior vena cava required the injection of 8 to 10 ml. of diodrast, when the balloon was above the renal veins, and 4 to 7 ml. when it was below the renal veins. Comparable pressures in the superior vena cava were obtained by the injection of 6 to 8 ml. of diodrast. At times, the inflated balloon was observed to occlude the vena cava entirely, as indicated by a change in shape of the balloon from a circular to a cylindrical outline and by a rise in distal venous pressure to 350 mm. saline or above. Such complete occlusions have been avoided and when recognized have been rectified immediately by deflating the balloon until it resumed its circular outline.

Rupture of the inflated balloon in a vein has not, thus far, occurred. In one subject the balloon was observed to deflate slowly after it had reached moderate size. The catheter was removed and on examination the balloon was found to have a "pin hole" leak, which became the site of rupture when the balloon was test-inflated rapidly and fully. This experience emphasizes the need for careful examination and test-inflation of the balloon before each use. The life of a balloon has proven to be short. After being used seven to ten times a

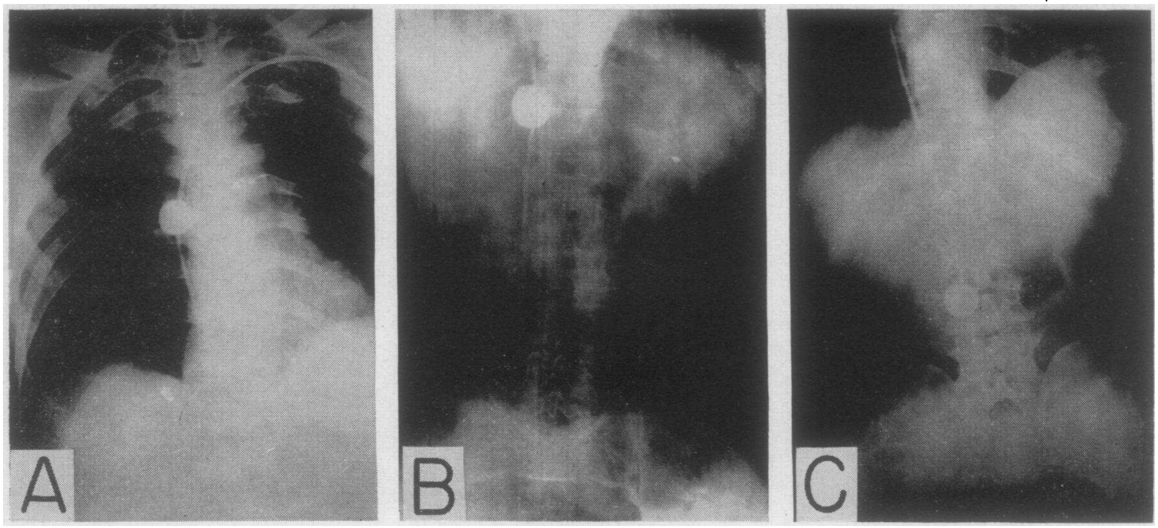

FIG. 2. X-RAYS SHOWING IDENTIFICATION AND POSITIONING OF THE INFLATED BALLOON

A. Superior vena cava. *B*. Inferior vena cava above the renal veins. *C*. Inferior vena cava below the renal veins.

balloon becomes worn and weakened and must be replaced.

The latex-rubber appears not to irritate the veins unduly. Local thrombosis of the peripheral vein of the arm has been the rule but only occasionally has it been of greater extent or severity than that seen after routine cardiac catheterization. One patient died from his primary disease one month after a study in which the balloon had been inflated in the inferior vena cava. On post-mortem examination the vena cava and its tributary veins were entirely normal.

OBSERVATIONS

The balloon has been inflated in the venae cavae of 49 patients without significant untoward effects. In the first nine subjects the period of inflation of the balloon was limited to 10 minutes. Subsequently, the duration of inflation was increased to a mean time of approximately 30 minutes and several intermittent inflations of such duration have been carried out over a two to four hour period in the same patient. The longest single period of inflation has been 50 minutes and the duration is being steadily and cautiously increased. In the last 43 observations the balloon has been inflated for periods of 20 to 40 minutes in 40 patients as follows: in the superior vena cava in 14 patients, in the inferior vena cava above the renal veins in 16

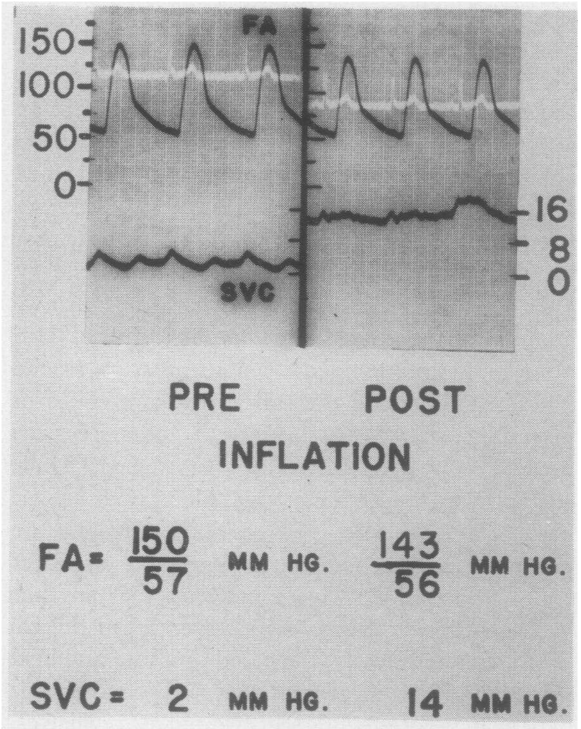

FIG. 3. FEMORAL ARTERIAL PRESSURE, SUPERIOR VENA CAVAL PRESSURE AND ELECTROCARDIOGRAM (LEAD II) BEFORE AND DURING INFLATION OF THE BALLOON IN THE SUPERIOR VENA CAVA

In this instance the balloon was about the distal opening, while the proximal opening was free for the measurement of pressures.

patients and in the inferior vena cava below the renal veins in 13 patients. The initial and final venous pressures, distal to the balloon, in these subjects are plotted in Figure 4.

COMMENT

Although venous congestion has, thus far, been produced only in the venae cavae, the application of the "balloon" catheter may be considerably wider. It seems quite feasible to use the method, or modifications of it, to produce venous congestion in any organ, the vascular tree of which is accessible to venous catheterization.

Details of construction of "balloon"

A "balloon" catheter of the type here described is manufactured by the United States Catheter and Instrument Corp. and has been used in animal studies (6). In our hands this catheter proved unsatisfactory in the larger veins of man, hence details of manufacture of the "balloon" catheter here used are described.

Preparation of catheter. A standard double lumen intracardiac catheter is scrupulously cleaned by soaking for 20 to 30 minutes in one liter of hot water containing 5 ml. of "Detergicide,"[2] after which the catheter is rinsed in tap water and then distilled water. To prevent liquid latex from entering the catheter during dipping, the proximal opening is sealed with a small piece of parafilm and the distal opening is closed by hanging from the distal tip a small rubber bulb containing 2 to 3 ml. of mercury. The weighted bulb minimizes swaying of the catheter during dipping.

Dipping the catheter. The desired thickness of rubber and a firm fit of latex on the catheter is obtained by dipping the entire catheter, first in a saturated solution of calcium nitrate in absolute ethyl alcohol and then immediately in centrifuged latex.[3] In order to obtain a stronger layer of rubber around the proximal opening, the distal one-third of the catheter is re-dipped in the calcium nitrate solution. Finally, the entire length of the catheter is dipped in prevulcanized latex.[3] Centrifuged latex is used for its firm fit around the catheter, prevulcanized latex because it is "strong" and smooth when dry. The various dippings are carried out without pause or drying.

[2] Detergicide—a quaternary ammonium compound with high surface tension lowering properties, manufactured by U. S. Catheter & Instrument Corp., Glens Falls, N. Y.

[3] Generously supplied by Mr. H. Berger of Stein Hall & Co., New York City.

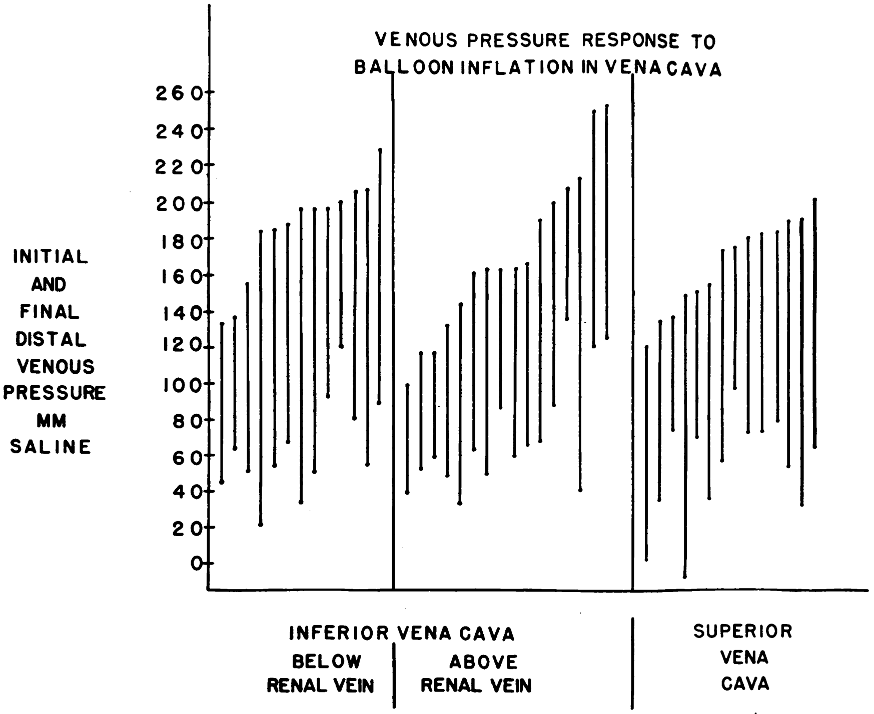

FIG. 4. INCREASE IN DISTAL VENOUS PRESSURES DURING INFLATION OF BALLOON IN THE SUPERIOR AND INFERIOR VENAE CAVAE OF FORTY SUBJECTS

Each vertical line connects the initial (lower point) and final (upper point) venous pressures of one subject. The designations along the abscissa indicate the site of the inflated balloon.

Drying and curing. The catheter is now dried in a warm box, heated with a 200 watt bulb, until the rubber is transparent. The latex is then cured by placing the catheter for 20 minutes in an electric oven at 90° C. In order to eliminate possible pyrogens in the rubber, the catheter with its rubber coating is soaked in cool 1N NaOH for one hour. It is then thoroughly washed in tap and distilled water and again dried in the warm box.

Tying the balloon. Temporary ties are applied above and below the proximal opening, and the rubber between the ties is distended by injecting water through the proximal lumen. An eccentric balloon forms. The balloon is deflated and the ties removed. The previously distended portion of the rubber is now pulled downward and fixed 1.5 cm. above and below the proximal opening by permanent ties of fine silk suture thread. The balloon when inflated is now symmetrical. The ties are fashioned by making a row of winds, pulling the free end under the winds, and securing it with a surgical knot. The rubber distal to the lower tie is cut and removed along with the rubber bulb, still hanging on the distal tip. The ties are then made more secure by applying to them a thin layer of varnish.

The balloon thus produced cannot slip off the catheter since the balloon is part of a rubber sheath which encases the entire catheter.[4] The capacity of the balloon is 8 ml. to 12 ml. of liquid and it inflates and deflates easily.

Sterilization. Sterilization is accomplished, at room temperature, by soaking the catheter and balloon, inside and out, in a solution of 5 ml. of "Detergicide" in a liter of distilled water. Wet heat weakens the rubber.

Stylette. In order to give rigidity to the catheter and prevent the balloon from "riding up" when it is in the inferior vena cava, a stylette of 0.020 inch stainless steel wire is used. It is inserted into the proximal-lumen section of the catheter until the proximal end of the wire is just flush with the hub of this lumen. Into the hub and over the wire end is then meshed a metal two-way stopcock which accommodates the syringe used to inject diodrast solution into the balloon. With the stopcock in the "off" position the inflation of the balloon is readily maintained.

[4] A recent development, used in 12 patients and *still on trial,* fashions a balloon about the proximal opening only and eliminates the rubber sheath encasing the rest of the catheter.

SUMMARY

A double lumen intracardiac catheter, equipped with a rubber balloon about the proximal opening, has been used to produce venous pressures up to 250 mm. saline in the superior and inferior venae cavae of man. This procedure has been performed on 49 patients without significant untoward effects. The balloon should be inflated slowly, for sudden, too rapid inflation to a marked degree may so obstruct venous return that syncope may result.

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